JUN 2 9 2000

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K001227

Applicant information:

Date Prepared:	April 14, 2000
Name:	**Opti-Center Laboratories Inc.**
Address	4375 Ouimet Street Sherbrooke (Quebec) Canada JIL 1X5
Contact Person:	Robert Mercure
Phone number:	(819) 564-8114
USA Consultant:	Martin Dalsing
Phone number	(970) 243-5490

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear
Trade Name:	**Ultra Vue 55/P & C (methafilcon A) Soft (Multifocal, Spherical, & Toric) Daily Wear Contact Lens (Clear & Blue Visibility Tint, Lathe-cut from Lens Blank)**

Equivalent Devices:

The Ultra Vue 55/P & C (Multifocal), Resolution 55 (Spherical) and Ultra Gel 55 (Toric) (methafilcon A) Soft Contact Lens for Daily Wear (clear, Lathe-cut) is substantially equivalent to the following predicate devices in terms of intended use and design. Predicate devices include: the Ultra Vue/P, Ultra Vue/C manufactured by Opti-Center Laboratories and the Resolution 45 & Ultra Gel manufactured by Opti-Center.

Device Description:

The Ultra Vue 55/P & C (Multifocal), Resolution 55 (Spherical) and Ultra Gel 55 (Toric) (methafilcon A) Soft Contact Lens for Daily Wear (clear, Lathe-cut) are fabricated from methafilcon A, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The (methafilcon A) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped; however, it will return to its proper configuration when completely rehydrated in the proper storage solution

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 55% water by weight. The physical properties of the lens are:

Refractive Index	1.515 (dry) 1.404 (hydrated)
Light Transmission (clear)	greater than 95% T
Water Content	55 % ± 2%
Specific Gravity	1.099 (hydrated)
Oxygen Permeability	18.2×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method).

Intended Use:

The **UltraVue 55/P & C (Multifocal) (methafilcon A)** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic. The lens may be worn by persons who exhibit astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity. The lens may be disinfected using a chemical disinfecting system.

The **Resolution 55 (Spherical) (methafilcon A)** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity. The lens may be disinfected using a chemical disinfecting system.

The **Ultra Gel 55 (Toric) (methafilcon A)** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10 diopters. The lens may be disinfected using a chemical disinfecting system.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a quality assurance program. The device will undergo manufacturing, packaging and sterilization procedures similar to devices currently marketed and distributed by Opti-Center Laboratories, Inc. The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the device is equivalent to the Resolution 45 & Ultra Gel 510(k) #K983496 and the Ultra Vue/P, Ultra Vue/C 510(k) #K974599. Being similar with respect to indications for use, materials, physical construction and safety & effectiveness to the predicate devices, this meets the requirements per section 510(k) of the act regarding substantial equivalence and *does not raise* different questions of safety and effectiveness than the predicate devices identified above.

The following matrix illustrates that the production method, lens function and material of the Ultra Vue 55/P & C (Multifocal), Resolution 55 (Spherical) and Ultra Gel 55 (Toric) (methafilcon A) Soft Contact Lens for Daily Wear (clear, Lathe-cut), are substantially equivalent to the predicate devices. In addition, the water content, polymer, DK value, refractive index, specific gravity, and light transmission are as well substantially equivalent to the predicate devices.

Substantial Equivalence Matrix

	Characteristic	UltraVue 55/P & C	Resultion 55	UltraGel 55	PREDICATE DEVICES
1.)	INDICATION	Correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic. The lens may be worn by persons who exhibit astigmatism of .75 diopter or less where the astigmatism does not interfere with visual acuity.	Correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic. The lens may be worn by persons who exhibit astigmatism of .75 diopter or less where the astigmatism does not interfere with visual acuity.	Correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic. The lens may be worn by persons who exhibit astigmatism of .75 diopter or less where the astigmatism does not interfere with visual acuity.	Correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic. The lens may be worn by persons who exhibit astigmatism of .75 diopter or less where the astigmatism does not interfere with visual acuity.
2.)	INTENDED USE	Daily Wear, Soft (hydrophilic) Contact Lens	Daily Wear, Soft (hydrophilic) Contact Lens	Daily Wear, Soft (hydrophilic) Contact Lens	Daily Wear, Soft (hydrophilic) Contact Lens
3.)	DESIGN TYPE	**Simultaneous Vision** Multifocal (distance, intermediate, near)	Spherical	Toric	**Simultaneous Vision** Multifocal (distance, intermediate, near) and/or Spherical or Toric
a.	Posterior Surface	Spherical in nature	Spherical in nature	Toric in nature	Spherical and Toric in nature
b.	Anterior Surface	Spherical/Aspheric in nature	Spherical in nature	Spherical in nature	Spherical and/or Aspheric in nature
c.	Multifocal Zone Design	Distance in Center/ Near in Center	N/A for Spherical	N/A for Toric	Distance in Center/ Near in Center
d.	Central Zone	Spherical	N/A for Spherical	N/A for Toric	Spherical & Aspheric
e.	Annular Zone	Aspherical (Intermediate/ Distance & Near Vision)	N/A for Spherical	N/A for Toric	Aspherical (Intermediate/ Distance & Near Vision)
f.	Toricity Area	N/A for UltraVue 55 P & C	N/A for Spherical	Posterior surface (central area of the posterior surface).	Posterior surface (toric), N/A (spherical), N/A for UltraVue P & C
g.	Ballast	N/A for UltraVue 55 P & C	N/A for Spherical	"Offset Prism Balast" stability feature	Double Slab-off for Toric, N/A for spherical, N/A for UltraVue P & C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 9 2000

Opti-Center Laboratories, Inc.
c/o Mr. Martin Dalsing
Medvice Consulting Inc.
623 Glacier Drive
Grand Junction, Co 81503

Re: K001227
Trade Name: UltraVue 55/P & C (Multifocal), Resolution 55 (Spherical) and Ultra Gel 55 (Toric) (methafilcon A) Soft Contact Lens for Daily Wear (clear, Lathe-cut)
Regulatory Class: II
Product Code: 86 LPL
Dated: April 14, 2000
Received: April 17, 2000

Dear Mr. Dalsing:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

Device Name: **UltraVue 55/P & C (Multifocal), Resolution 55 (Spherical) and Ultra Gel 55 (Toric) (methafilcon A) Soft Contact Lens for Daily Wear (clear, Lathe-cut).**

INDICATIONS FOR USE:

The **UltraVue 55/P & C (Multifocal) (methafilcon A)** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic. The lens may be worn by persons who exhibit astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity. The lens may be disinfected using a chemical disinfecting system.

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(PLEASE DO OT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W. C. Brown, PH.D.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K001227

Prescription Use X or Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)